Message

From: Wozniak, Chris [wozniak.chris@epa.gov]

Sent: 2/2/2016 6:04:41 PM

To: Kough, John [Kough.John@epa.gov]

Subject: RE: Oxitec's draft EA review

Attachments: Oxitec draft EA review-CAW-012916.docx

Here is the draft EA with my comments noted in case you want to look it over. Nothing egregious or exciting herein, just some clarifications and suggested edits. Hope to wrap the FONSI by 3...

From: Kough, John

Sent: Tuesday, February 02, 2016 1:02 PM **To:** Wozniak, Chris <wozniak.chris@epa.gov>

Subject: RE: Oxitec's draft EA review

Okee dokee

From: Wozniak, Chris

Sent: Tuesday, February 02, 2016 12:53 PM
To: Kough, John < Kough. John@epa.gov >
Subject: RE: Oxitec's draft EA review

3pm works, so do earplugs:0 I'll call you a little after 3 then....

From: Kough, John

Sent: Tuesday, February 02, 2016 12:52 PM **To:** Wozniak, Chris < wozniak.chris@epa.gov >

Subject: RE: Oxitec's draft EA review

I have a MPB meeting to get yelled at about not meeting PRIA timeframes. How about 3PM? If that's too late let's just talk on Wednesday if you're coming in. Up to you.

JK

From: Wozniak, Chris

Sent: Tuesday, February 02, 2016 12:50 PM
To: Kough, John < Kough. John@epa.gov >
Subject: FW: Oxitec's draft EA review

Marching through the EA, then the FONSI. Want to chat about 2pm?

From: Dass, Brinda [mailto:Brinda.Dass@fda.hhs.gov]

Sent: Monday, February 01, 2016 1:59 PM

To: Wozniak, Chris <wozniak.chris@epa.gov>; Evdokimov, Evgenij A <Evgenij.Evdokimov@fda.hhs.gov>; Kough, John

<Kough.John@epa.gov>

Subject: RE: Oxitec's draft EA review

Thanks so much Chris. We know you are definitely looped in on the Zika front and feel some of the same warm glow that it carries in its wake. Will wait to hear back from you on comments to the EA. Whenever you do get a chance if you could take a look at the protocol for the trial that was sent a week or so after that EA that would help a lot to. The sponsor would like to get protocol concurrence from the FDA and interagency expert group as well.

Cheers Brinda

From: Wozniak, Chris [mailto:wozniak.chris@epa.gov]

Sent: Monday, February 01, 2016 1:55 PM **To:** Evdokimov, Evgenij A; Kough, John

Cc: Dass, Brinda

Subject: RE: Oxitec's draft EA review

Evgenij,

I am working through the documents and will have some comments tomorrow but John and I thought it best that we compare notes prior to sending on so we are on the same page so to speak. I know John is out of the office at meetings today and tomorrow so we will touch base Wednesday to formalize an EPA response. I'll let you know then exactly when that will be. Had a call with NIAID this morning on Zika and I can understand the pressures facing all relative to this virus. It certainly has lit a fire under many!

Chris

From: Evdokimov, Evgenij A [mailto:Evgenij.Evdokimov@fda.hhs.gov]

Sent: Monday, February 01, 2016 1:38 PM

To: Wozniak, Chris < wozniak.chris@epa.gov >; Kough, John < Kough.John@epa.gov >

Cc: Dass, Brinda < Brinda. Dass@fda.hhs.gov>

Subject: Oxitec's draft EA review

Dear colleagues,

I just wanted to touch base with you and check on the progress of the comments/edits for the Oxitec's draft EA, review, and FONSI. Zika virus is bringing a lot of pressure on us so if you could send us your comments as soon as possible we would greatly appreciate it. Please let me know if you have any questions.

Thank you,

Evgenij

Evgenij Evdokimov, PhD Biologist Animal Biotechnology Interdisciplinary Group, HFV-2 USFDA Center for Veterinary Medicine 7500 Standish Place Rockville, MD 20855

Phone: 240-402-0712 Fax: 240-276-8359

Evgenij.Evdokimov@fda.hhs.gov